



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/472,558	12/27/1999	MOHAMMAD B. BAHRAMIAN	2281/102	8925

2101 7590 06/01/2004
BROMBERG & SUNSTEIN LLP
125 SUMMER STREET
BOSTON, MA 02110-1618

EXAMINER

PARAS JR, PETER

ART UNIT	PAPER NUMBER
----------	--------------

1632

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/472,558	Applicant(s) BAHRAMIAN ET AL.	
	Examiner Peter Paras, Jr.	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11, 14, 28-49, 51, 53-56 and 58-60 is/are pending in the application.
- 4a) Of the above claim(s) 28-49, 51, 53-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 14 and 58-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1632

Applicant's amendment received on 3/10/04 has been entered. Claims 11, 14 and 58-60 have been amended. Claims 57 and 69-84 have been cancelled. Claims 11, 14, 28-49, 51, 53-56, and 58-60 are pending. Claims 11, 14 and 58-60 are under current consideration.

Election/Restrictions

Claims 28-49, 51 and 53-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5.

Oath/Declaration

The substitute declaration received on 3/22/04 has been entered.

Claim Objections

The previous objection to claim 80 has been withdrawn as the claim has been cancelled.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The previous rejection of claims 70-79 and 81-83 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter) has been withdrawn as the claims have been cancelled.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The previous rejection of claims 57-60, 71-76 and 80-84 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn in light of the amendments to claims 58-60 and the cancellation of claims 57, 71-76 and 80-84.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting

Art Unit: 1632

directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 11 as amended is rejected under 35 U.S.C. 102(e) as being anticipated by Fire et al. The previous rejection is maintained for the reasons of record advanced on pages 6-7 of the Office action mailed on 11/10/03.

Applicant's arguments filed 3/10/04 have been fully considered but they are not persuasive. Applicants have argued that Fire deals primarily with double-stranded RNA for inhibition of target sequences. Applicants assert the two places in Fire discussing involvement of DNA are merely theoretical. Applicants submit the discussions of Fire relating to use of DNA are nothing more than highly dubious proposals. See pages 15-16 of the amendment.

In response, the Examiner asserts the relevance of Applicant's arguments is not understood since every patent is presumed valid (35 U.S.C. 282), and that presumption includes the presumption of operability (*Metropolitan Eng. Co. v. Coe*, 78 F.2d 199, 25 USPQ 216 (D.C.Cir. 1935)). Also see MPEP 716.07. Further, since in a patent it is presumed that a process if used by one skilled in the art will produce the product or result described therein, such presumption is not overcome by a mere showing that it is possible to operate within the disclosure without obtaining the alleged product. In re Weber, 405 F.2d 1403, 160 USPQ 549 (CCPA 1969). It is to be presumed also that skilled workers would as a matter of course, if they do not immediately obtain desired results, make certain experiments and adaptations, within the skill of the competent

worker. The failures of experimenters who have no interest in succeeding should not be accorded great weight. In re Michalek, 162 F.2d 229, 74 USPQ 107 (CCPA 1947); In re Reid, 179 F.2d 998, 84 USPQ 478 (CCPA 1950).

Applicants argue nothing in Fire anticipates the presently disclosed invention, which requires a ds-DNA muting composition that mutes a target gene in an animal system independent of the level of expression of the muting DNA. Applicants submit that "just for the record" the actual examples in the presently disclosed application are for mammals, not worms as in Fire et al. Applicants go on to assert that at the time the instant application was filed no one had ever succeeded in muting expression of an endogenous gene in a mammalian system-not Fire, not anyone, even with RNAi, in spite of the claims in Fire et al, which suggest otherwise. See page 16 of the amendment.

In response, the Examiner maintains that Fire anticipates the claimed invention. As pointed out in the Office action mailed on 11/10/03 (see page 7), Fire has disclosed use of DNA (see columns 12-13). Also see column 8, in the paragraph bridging to column 9. In fact, Fire makes clear that regulatory regions (now included in the claim as amended) should be included as part of the introduced [DNA] transgene or expression construct to direct transcription. See column 8, in the paragraph bridging to column 9. Furthermore, the phrase "wherein such muting is independent of the level of expression of the muting DNA" is not interpreted to mean that muting DNA is not expressed. It is interpreted to merely mean that muting occurs regardless of the level at which the muting DNA is expressed. The claim as written leaves open the possibility of

Art Unit: 1632

expression of muting DNA and is therefore properly anticipated by Fire. Also, in response, to Applicant's "just for the record" comment, the Examiner would like to point out that Applicant's response in its entirety is part of the record. It is not understood which parts of the response are not to be included as part of the record. Finally, it is maintained that Fire teaches use of animal cells in accordance with his methods. The animal cells may include mammalian cells. See the Office action mailed on 11/10/03, on page 7 and also column 8 of Fire. Applicant's arguments appear to imply that Fire is an invalid patent. Applicants are reminded that a response to an office action is not the proper venue/forum for invalidating an issued patent.

Accordingly, the rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11, 14 and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fire taken with WO 94/11494. The previous rejection is maintained for the reasons of record advanced on pages 8-10 of the Office action mailed on 11/10/03.

Applicant's arguments filed 3/10/04 have been fully considered but they are not persuasive. Applicants have argued Fire is not relevant with respect to the muting DNA

Art Unit: 1632

compositions of the presently claimed invention therefore it would not be obvious to combine the teachings of Fire with WO 94/11494 to arrive at the claimed invention. See page 17 of the amendment.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case motivation to combine the references is simple. WO 94/11494 teaches methods of inhibiting expression of the human or mouse $\alpha 1(I)$ procollagen gene. Fire taught that RNA interference has advantages over antisense interference and that such can be applied to any gene of interest. Therefore, it would have been obvious to combine the references to inhibit expression of $\alpha 1(I)$ procollagen gene for treating collagen related diseases as discussed by WO 94/11494. See pages 8-9 of the Office action mailed on 11/10/03. It is maintained that Fire is relevant with respect to the muting DNA compositions of the claimed invention. See the 102(e) rejection above.

Accordingly, the rejection is maintained for the reasons of record.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1632

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is (571) 272-0732. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Official Fax Center number is (703) 872-9306.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (571) 272-0532.

Peter Paras, Jr.

PETER PARAS, JR.
PRIMARY EXAMINER

Art Unit 1632

A handwritten signature in black ink, appearing to read "Pete Paras, Jr.", written in a cursive style.